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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/300,482	04/28/1999	NORDINE CHEIKH	04983.0031.U	4511

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EXAMINER	
MORAN, MARJORIE A	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 07/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/300,482	CHEIKH ET AL.	
	Examiner	Art Unit	
	Marjorie A. Moran	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,11-13,15-22,24,28 and 30-39* is/are pending in the application.

4a) Of the above claim(s) *32-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 11-13, 15-22, 24, 28, and 30-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/24/06 has been entered.

Claims 1, 11-13, 15-22, 24, 28, and 30-39 are pending. All rejections and objections not reiterated below are hereby withdrawn.

Election/Restrictions

Claims 32-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Invention designated as Group IV (transgenic plants) in the restriction requirement mailed 9/20/2000, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed as Paper No. 7 on 10/6/2000.

An office action on the merits of elected claims 1, 11-13, 15-22, 24, 28, and 30-31 follows.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 11-13, 15-22, 24, 28 and 30-31 are again rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility. The arguments and Vosnidou declaration filed 4/24/06 have been fully considered but are not persuasive.

Applicant's arguments with regard to uses of the claimed nucleic acids to identify polymorphisms, or to transform plants, as set forth on pages 8-9 of the response, are not persuasive as these are generic uses applicable to the broad class of nucleic acids, and are not specific to the particular sequences recited in the instant claims. None of the recited sequences are disclosed as comprising a polymorphic site, nor are any of the claimed sequences disclosed as being differentially expressed in a particular tissue or at a particular stage of development such that the sequences may be used to identify of distinguish something specific or "of immediate benefit to the public" with regard to the plants thus transformed. Applicant is reminded that a "use" to perform further research (e.g. to identify a polymorphism, which THEN may be correlated to a specific phenotype, or to identify an associated phenotype in a plant) is not a utility under 35 USC 101.

As set forth in previous office actions, where a nucleic acid does not, in itself, have a utility, utility maybe established based on a polypeptide encoded. In accordance with this, applicant argues that the claimed nucleic acids have utility because they "correlate" to underlying genes in the phosphogluconate pathway and/or encode recited maize or soybean genes. In response to the repeated argument that the claimed sequences encode phosphogluconate pathway enzymes, it is again noted and maintained that the specification does not actually disclose that any of the claimed SEQ ID NO's is known to encode a protein or

peptide, specifically one of the enzymes recited in the claims. For the nucleic acid to have utility based on a putatively encoded peptide, the identity and activity of the peptide must be known or established. Contrary to applicant's arguments, the specification does not, in fact, disclose ANY amino acid sequences, specifically ones encoded by the claimed nucleic acids. The only "evidence" supporting applicant's argument that the claimed nucleic acids encode enzymes is set forth in the instant specification is found in Table A, pages 224-242. Table A discloses, for example, that SEQ ID NO: 1 is PREDICTED to encode a polypeptide with 58% homology to a dehydrogenase. The Vosnidou declaration provides evidence that instant SEQ ID NO: 1 has 95% identity to a corn embryo gene which is "similar" to a glucose-6-posphate dehydrogenase mRNA sequence. Neither the Vosnidou declaration or the NCBI record teach how "similar" the corn embryo sequence actually is to the dehydrogenase, nor how it is similar (e.g. no degree of identity or homology is set forth), nor are any homology parameters provided, and there is no teaching that conserved domains specific to dehydrogenases are encoded, etc. such that one skilled in the art would conclude that the NCBI sequence does indeed encode a dehydrogenase. Similarly, there is no evidence anywhere with regard to actual activity, conserved domains, catalytic domains encoded, etc. for the instantly claimed sequences that would lead one skilled in the art to conclude that the claimed sequences do indeed encode peptides or proteins with any activity, specifically that of the enzymes argued by applicants and recited in the claims. Thus, in the absence of further experimentation, and using sound scientific reasoning, one skilled in the art would not be able to ascertain with any degree of certainty whether the claimed nucleic acids do, in fact encode the claimed enzymes.

In response to the argument that the examiner has not provided support for the assertion that "for a nucleic acid to have utility based on a putatively encoded peptide, the identity and activity of the peptide must be known or established," support is found in MPEP 2107, under

the discussion of a "substantial utility." It is noted that the examiner has previously stated that where a claimed nucleic acid, per se, does not have utility (e.g. as a promoter), it may have utility based on the encoded peptide. In that case, the utility is assessed based on the utility of the peptide so encoded. MPEP 2107 states that an example of a product which lacks substantial utility is: "an intermediate product for use in making a final product that has no specific, substantial and credible utility." In the instant case, the claimed nucleic acids are interpreted to be "intermediate products" for use in making "final products"; i.e. peptides.

In response to the argument that the claims also recite "fragments", thus a complete ORF is not necessary, it is again noted that a fragment of a protein, wherein the fragment itself does not have utility or activity, does not necessarily have a utility.

Also contrary to applicant's repeated arguments, the examiner again asserts that she has NOT stated that an ORF or knowledge of an appropriate ATG codon is necessary. However, where the utility of a nucleic acid sequence rests on the utility of an encoded protein, knowledge of an ORF or appropriate ATG would *be helpful* to one skilled in the art to determine what, if any peptide may be expressed by a particular nucleic acid sequence. In response to the argument that applicants has provided a "reasonable correlation" between the claimed nucleic acid sequences and encoded enzymes, it is again noted that there is no evidence in the instant specification, and none has been filed to show or support that any of the claimed nucleic acids do, in fact, encode ANY peptide, specifically one with enzymatic activity.

For all the reasons previously set forth and set forth above, the rejection is maintained.

Claims 1, 11-13, 15-22, 24, 28 and 30-31 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by a specific, substantial, and credible utility or a well-established utility for the reasons set forth above, one skilled in the

art would not know how to use the claimed invention. As the utility rejection is maintained, so is the enablement rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 22, 24 and 28 are again rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is a LACK OF ENABLEMENT rejection.

Applicant's arguments filed 4/24/06 have been fully considered, but are not persuasive. In response to the argument that the specification "provides a detailed description of the nucleic acid sequences required by the claims, and further describes amino acid sequences there from," it is noted that (a) the rejection is not one of lack of written description, and (b) the specification does not, in fact, disclose any amino acid sequences anywhere. Applicant points to pages 46-52 for a "description" of polypeptide molecules. While these pages do provide a list of enzymes by generic name, they do NOT provide a description or listing of amino acid SEQUENCES. AS previously set forth, the instant specification does not teach that the claimed nucleic acids are known to encode polypeptides with enzymatic activity. Also as set forth above, none of the claimed nucleic acids appears to be long enough to encode the entirety of any of the enzymes recited in the claims. Further, it is not known whether any encoded fragment of a polypeptide would have enzymatic activity. The instant specification does not

disclose any comparison of conserved regions, catalytic domains, etc., between known enzymes and putatively encode peptides such that one skilled in the art would be able to determine whether the instantly claimed polynucleotides actually encode polypeptides with enzymatic activity. In response to the argument that the ORFs are not required for enablement, it is noted that the examiner stated that ORFs would be *helpful* in determining whether a claimed polynucleotide does, in fact, encode a recited enzyme, or any fragment thereof. However, even knowledge of an ORF may not be sufficient to determine whether a polynucleotide does indeed encode a polypeptide with the recited enzymatic activity. While it is admitted that routine and well-known steps do not constitute "undue experimentation," it is noted that in the instant case, one skilled in the art must guess at a reading frame for translation, must determine an appropriate expression format (cells? what type? cell-free?), must generate an expression vector or cassette with an appropriate promoter, etc., must determine the appropriate conditions for expression, including those required for post-translational processing (and must determine whether such processing is necessary), must guess at appropriate isolation procedures, and must determine how to do all of the above without losing putative enzymatic ability (e.g. many expression systems can; but do not always result in N-terminal blockage, and thus, no activity of the expressed protein). After a presumed peptide is expressed and isolated, presumably under conditions which do not result in loss of activity, one skilled in the art must then determine conditions under which to test for the claimed activity, and must know what particular conditions of salt, temperature, co-factors are required for the particular enzymatic activity being assayed. The examiner maintains that the totality of guesswork and experimentation required to determine whether any of the claimed nucleic acids does indeed encode a peptide with enzymatic activity constitutes undue experimentation. For these reasons

and those previously set forth, the examiner maintains that one of skill in the art would not know how "to use" the claimed nucleic acids to encode an enzyme, as claimed.

35 U.S.C. 112, Written Description Rejection

Claims 1, 22, 24, and 28 are again rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses SEQ ID NO's 1, 4, 14, 27, 225, 298, 311, 356, 569, and 619. which putatively encode various phosphogluconate pathway enzymes. Claims 1, 22, 24 and 28 are specifically directed to encompass sequences that encode a variety of enzymes. As the sequences recited in the claims are apparently fragments which do not appear to comprise ORF's or actually encode any known proteins, a nucleic acid "comprising" the fragments encompasses much larger sequences which may encode entirely different proteins with entirely different activities from those of the recited enzymes.

Applicant argues the disclosure need only show that applicant was in possession of the claimed inventions, and insists that the instant specification does so. In response, it is noted that the specification does not, in fact, actually describe any nucleic acid KNOWN to encode an entire enzyme, and therefore does not describe nor show possession of the claimed invention of at least claims 1, 22, 24, and 28.

The argument that the examiner "appears to assert that each nucleic acid molecule within a claimed genus must be described by its complete structure" is confusing, as the instant rejection is not made with regard to description of a "complete structure" nor to any genus. It is noted, as recognized by applicants in the response on page 18, that the rejection with regard to

description of "broader" embodiments of the claimed nucleic acids was withdrawn in the previous office action. The instant rejection is made over a lack of description for nucleic acids known to actually encode a peptide with enzymatic activity.

For all of the reasons set forth above and previously set forth, the rejection is maintained.

Double Patenting

The rejection over 10/425,114 is herby withdrawn in view of amendments to the claims of '114 filed 6/22/06.

The rejection over 10/425,115 is hereby withdrawn in view of amendments to the claims of '115 filed 5/30/06.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Monday-Friday; 6 am-2:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marjorie A. Moran
Primary Examiner
Art Unit 1631

Marjorie A. Moran
7/10/06